PCT Chapter II

26th November 2001/ch

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International Patent Application PCT/EP 00/08 382
based on DE 199 40 717.7
Curasan AG
Heide et al.;
resorbable bone replacement and bone formation material

Patent claims

1. Resorbable bone replacement and bone formation material (augmentation material) based on porous β-tricalcium phosphate (β-TCP), which **can be produced** by

   (a) baking a phosphate powder of a chemical composition the residue on baking of which yields theoretically chemically pure tricalcium phosphate and

   (b) providing the baked blanks with tubular pores,

   characterised in that
   β-tricalcium phosphate (β-TCP) is baked at least twice and especially at least three times and the formation of the thermodynamically stable adjacent phases of β-TCP is prevented by

(i) powdering the presynthesis product obtained according to step (a),

(ii) optionally baking the powdered presynthesis product together with phosphate powder according to step (a) and powdering the material obtained and optionally repeating step (ii) once or more than once,

(iii) compressing the powdered product obtained in step (i) or step (ii) together with phosphat powder according to st p (a) to form blanks and subj cting the blanks formed to final ceramic baking and

(iv) subjecting the compressed or baked blanks, at least 99.5 % of which consists of pure β-tricalcium phosphate (β-TCP), to step (b).

2. Formation material according to claim 1, **characterised** in that the chemical and crystalline purity, the fabric structure, the microporosity and the macroporosity of the augmentation material make possible rapid, foreign-body-reaction-free, biochemically orientated integration and resorption in bone.

3. Formation material according to one of the preceding claims, which can be produced by

(i) starting from a presynthesis product **obtainable** by baking a phosphate powder of a chemical composition the residue on baking of which yields theoretically chemically pure tricalcium phosphate as a presynthesis product, and powdering that presynthesis product,

(ii) optionally baking the powdered presynthesis product together with phosphate powder according to step (i) and powdering the material obtained and optionally repeating step (ii) once or more than once,

(iii) compressing the powdered product obtained in step (i) or step (ii) together with phosphate powder according to step (i) to form blanks and subjecting the blanks formed to final ceramic baking and

(iv) providing the compressed or baked blanks with tubular pores.

4. Formation material according to claim 1 or 3, **obtainable** by baking at a temperature below 1200°C in the β-tricalcium phosphat (β-TCP) phase region.

5. Formation material according to one of claims 1, 3 or 5, **obtainable** by using in step (ii) and/or step (iii) from 1 to 50 % by weight, especially from 1 to 25 % by weight, phosphate powder (based on the total weight of phosphate powder and already baked material).

6. Formation material according to one of the preceding claims, **characterised** in that the sintered structure has a uniform, interconnected microporosity having pore widths in the region of from 2 to 15 µm and especially from 4 to 10 µm and/or the matrix of the augmentation material is tightly sintered to microporosity, especially with microparticles that are loosely bound in the sintered structure and/or phagocytosable, having a diameter of max. 15 µm, being absent.

7. Formation material according to one of the preceding claims, **characterised** by a microporosity of 20 % by volume or more, preferably from 20 to 40 % by volume, and especially 30 % by volume or more, based on the overall porosity (consisting of micro- and macro-porosity).

8. Formation material according to one of the preceding claims, **obtainable** by providing the compressed blank with tubular pores with the aid of a compression mould of optionally more than one part.

9. Formation material according to one of the preceding claims, **obtainable** by providing the baked blank with tubular pores by means of milling or drilling.

10. Formation material according to one of the preceding claims, **characterised** in that the formation material is in block form, with 2- or 3-dimensionally oriented macroscopic tubular pores passing through each block, which are in each case arranged perpendicular to the block surface or to an imaginary plane laid through the block or against the block and form an interconnecting system of tubular pores.

11. Formation material according to claim 10, **characterised** in that a block intended for implantation, together with its tubular pores, can be so oriented for implantation or on processing prior to implantation that at least one direction of orientation of the tubular pores corresponds to a biomechanically or biofunctionally intended direction of growth.

12. Formation material according to one of the preceding claims, **characteri ed** by tubular pores that have radii in the region of from 100 to 2000 µm and especially from 500 to 2000 µm.

13. Formation material according to one of the preceding claims, **characterised** in that the formation material, present in block form, is penetrated by the tubular pores spaced apart at a defined spacing with respect to one another, especially at a spacing that corresponds to a wall thickness of not more than from 1500 to 4000 µm and especially from 2000 to 3000 µm.

14. Formation material according to one of the preceding claims, **characterised** by an overall porosity (consisting of micro- and macro-porosity) of more than 50 % by volume.

15. Formation material according to one of the preceding claims, **characterised** by a macroporosity of from 25 to 50 % by volume, and especially from 30 to 40 % by volume, based on the overall porosity (consisting of micro- and macro-porosity.

16. Formation material according to one of the preceding claims, **characterised** in that the block form is a simple geometric shape, especially that of a cube, cuboid, taper, cone or disc.

17. Formation material according to one of the preceding claims, **characterised** in that it is a semi-finished product, especially for subsequent mechanical processing, preferably for individual adaptation in the case of a bone defect in mouth or jaw medicine, orthopaedic surgery or trauma surgery.

18. Formation material according to one of claims 11 to 17, **characterised** in that the material is compressed, especially baked or sintered, only to a degree such that it can be processed using tools available to the practitioner, especially using a rasp, file, scalpel or a dentist's instrument.

19. Formation material according to one of claims 11 to 17, **characterised** in that it has been brought into the form of an individual prosthesis with the aid of a medical CAD/CAM method.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

I, ADRIAN PAUL BROWN, M.A., M.I.L., M.I.T.I., declare

1. That I am a citizen of the United Kingdom of Great Britain and Northern Ireland, residing at 5 Gilbert Road, London, SE11 4NZ.

2. That I am well acquainted with the German and English languages.

3. That the attached is a true translation into the English language of the attached German text filed at the US Patent and Trademark Office on 25th February 2002.

4. That all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardise the validity of the patent application in the United States of America or any patent issuing thereon.

DECLARED THIS 16th DAY OF APRIL 2002

A. P. Brown

A. P. BROWN